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| 10/045,866 | 10/29/2001 | Yuichi Komachi | | 1103 |

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EXAMINER

ROY, BAISAKHI

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3737

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,866

Applicant(s)

KOMACHI ET AL.

Examiner

Baisakhi Roy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/5/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 9-15 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 9-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Wach et al. (6487349).

Regarding claims 9 and 10, Wach et al. disclose an analysis system of matter inside of a vessel (col. 54 lines 16-29, col. 57 lines 10-25) with said system comprising a body with a portion with a window at the distal end extending from said body and

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capable of being inserted into the vessel, and a channel extending through the body and portion being inserted and reaching said window (col. 30 lines 4-22, col. 31 lines 47-67, col. 33 lines 8-20, col. 39 lines 28-67, col. 40 lines 1-9, col. 41 lines 66-67, col. 42 lines 1-10, col. 46 lines 62-65, col. 47 lines 58-65, col. 54 lines 40-43, col. 74 lines 50-67). The reference further teaches the use of a Raman analysis apparatus with a light source, a spectroscope, an insert cable inserted into said channel with its distal end faced with the window, an excitation optical fiber received in said cable or tubing with its basal end connected to the light source and distal end arranged at a central area of the distal end portion (col. 27 lines 5-13, col. 28 lines 17-63, col. 29 lines 50-63, col. 30 lines 4-23 lines 39-64). The reference further teaches a plural number of light receiving optical fibers being received in said cable or tubing and whose basal end are connected to said spectroscope and whose distal end are arranged in such a manner as to surround said excitation optical fiber at the distal end portion of the tubing (col. 22 lines 37-51, col. 28 lines 17-41 lines 59-63, col. 29 lines 50-63, col. 35 lines 35-49).

Wach et al. teach a film-like excitation filter adhered to the distal end of excitation optical fiber, a film-like filter adhered to the distal end of the receiving optical fiber, (col. 34 lines 18-67, col. 44 lines 21-65, col. 45 lines 12-29 lines 37-58, col. 46 lines 55-57, col. 47 lines 20-39, col. 49 lines 18-33, col. 50 lines 13-38, col. 52 lines 54-67, col. 64 lines 14-25) a light receiving plate with corresponding film-like filter adhered to it for excitation and receiving optical fibers, and a center hole in said light receiving plate with a transparent excitation small piece fitted into said center hole (col. 66 lines 57-67, col. 67 lines 1-45, col. 68 lines 60-67, col. 69 lines 1-27, fig. 79).

Regarding claim 11, Wach et al. recite that the endoscope is sized and shaped to fit within an artery or other blood vessel (col. 49 lines 4-32).

Regarding claim 12, Wach et al. disclose an analysis system of matter inside of a vessel (col. 54 lines 16-29, col. 57 lines 10-25) with said system comprising a body with a portion with a window at the distal end extending from said body and capable of being inserted into the vessel, and a channel extending through the body and portion being inserted and reaching said window (col. 30 lines 4-22, col. 31 lines 47-67, col. 33 lines 8-20, col. 39 lines 28-67, col. 40 lines 1-9, col. 41 lines 66-67, col. 42 lines 1-10, col. 46 lines 62-65, col. 47 lines 58-65, col. 54 lines 40-43, col. 74 lines 50-67). The reference further teaches the use of a Raman analysis apparatus with a light source, a spectroscope, an insert cable inserted into said channel with its distal end faced with the window, an excitation optical fiber received in said cable with its basal end connected to the light source and distal end arranged at a central area of the distal end portion (col. 27 lines 5-13, col. 28 lines 17-63, col. 29 lines 50-63, col. 30 lines 4-23 lines 39-64). The reference further teaches a plural number of light receiving optical fibers being received in said cable or tubing and whose basal end are connected to said spectroscope and whose distal end are arranged in such a manner as to surround said excitation optical fiber at the distal end portion of the tubing (col. 22 lines 37-51, col. 28 lines 17-41 lines 59-63, col. 29 lines 50-63, col. 35 lines 35-49). Wach et al. further teach the distal end of the excitation optical fiber to be slanted with respect to an axis of the bundle of light receiving optical fibers (abstract, col. 25 lines 5-7 lines 41-60, col. 26 lines 37-50, col. 27 lines 21-67, fig. 24-26).

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Regarding claims 13 and 14, Wach et al. teach a film-like excitation filter adhered to the distal end of excitation optical fiber, a film-like filter adhered to the distal end of the receiving optical fiber (col. 34 lines 18-67, col. 44 lines 21-65, col. 45 lines 12-29 lines 37-58, col. 46 lines 55-57, col. 47 lines 20-39, col. 49 lines 18-33, col. 50 lines 13-38, col. 52 lines 54-67, col. 64 lines 14-25).

Regarding claim 15, Wach et al. recite that the endoscope is sized and shaped to fit within an artery or other blood vessel (col. 49 lines 4-32).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al. (5293872) in view of Wach et al.

Regarding claims 9 and 10, Alfano et al. teach method and corresponding apparatus for distinguishing of matter adhered to an inside of a vessel using Raman spectroscopy. With reference to applicant's claim 9, figures 6 and 9 of Alfano et al. below clearly teach a guiding apparatus 109 including a main body, a flexible insert portion extending from said main body portion and having a window formed in a distal end thereof, and a channel extending through said main body portion and insert portion

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and reaching said window, said insert portion being able to be inserted into said vessel; said Raman analysis system including a flexible channel 125/80 to be inserted into said channel and whose distal end is faced with said window, an excitation optical fiber 81 and a light receiving fiber 83 which are both received in said insert cable, a light source 121/135 connected to basal end of said excitation optical fiber, and a spectroscope 127 connected to a basal end of said light receiving optical fiber', and an excitation light emitted from said light source 121/135 projected through said window via said excitation optical fiber 81 and Raman scattered by impinging on said matter adhered to the inside wall of said vessel, said scattered light being made incident to said window and spectrally analyzed by said spectrometer 127 via said light receiving optical fiber 83, and thus said matter adhered to the inside wall of said vessel being analyzed, column 7 through 9, more specifically column 7 lines 20-33 and column 8. With respect to claim 2 figures 6 (above) and 7 and column 7 lines 20-33 clearly diagram and discuss, respectively, a single number of said excitation optical fiber 81 and plural number of said light receiving optical fibers 83 and at a distal end portion of said insert cable, said single number of excitation optical fiber 81 is arranged at a central area thereof and said plural number of light receiving optical fibers 83 are arranged in such a manner as to surround said excitation optical fiber 81. Alfano et al. do not teach a film-like excitation filter adhered to the distal end of excitation optical fiber, a film-like filter adhered to the distal end of the receiving optical fiber, a light receiving plate with corresponding film-like filter adhered to it for excitation and receiving optical fibers, and a center hole in said light receiving plate with a transparent excitation small piece fitted into said center

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hole. Wach et al. disclose an apparatus for analyzing matter adhered to the inside wall of a vessel comprising a guiding apparatus and a Raman analysis apparatus with a film-like excitation filter adhered to the distal end of excitation optical fiber, a film-like filter adhered to the distal end of the receiving optical fiber, (col. 34 lines 18-67, col. 44 lines 21-65, col. 45 lines 12-29 lines 37-58, col. 46 lines 55-57, col. 47 lines 20-39, col. 49 lines 18-33, col. 50 lines 13-38, col. 52 lines 54-67, col. 64 lines 14-25) a light receiving plate with corresponding film-like filter adhered to it for excitation and receiving optical fibers, and a center hole in said light receiving plate with a transparent excitation small piece fitted into said center hole (col. 66 lines 57-67, col. 67 lines 1-45, col. 68 lines 60-67, col. 69 lines 1-27, fig. 79). It would have therefore been obvious to one of ordinary skill in the art to have deposited/adhered the film-like filters onto the ends of optical fibers as taught by Wach et al. into the probe system of Alfano et al. for the purpose of allowing effective and efficient manipulation of the light delivery and reception region during Raman analysis. It would have also been obvious to adhere film-like filters on the light plate/window of the probe with said plate having a center hole with a transparent excitation small piece through said center hole for the purpose of providing equivalent function of filtering the illumination and light detection and thereby improving Raman scattering analysis.

Regarding claim 11, Alfano et al. column 9 lines 9-28 recites that the endoscope 141 (interpreted as the guiding apparatus of the applicant) is sized and shaped to fit within an artery or other blood vessel.

Regarding claim 12, Alfano et al. teach a method and corresponding apparatus for distinguishing of matter adhered to an inside of a vessel using Raman spectroscopy. With reference to applicant's claim 12, figures 6 and 9 of Alfano et al. below clearly teach a guiding apparatus 109 including a main body, a flexible insert portion extending from said main body portion and having a window formed in a distal end thereof, and a channel extending through said main body portion and insert portion and reaching said window, said insert portion being able to be inserted into said vessel; said Raman analysis system including a flexible channel 125/80 to be inserted into said channel and whose distal end is faced with said window, an excitation optical fiber 81 and a light receiving fiber 83 which are both received in said insert cable, a light source 121/135 connected to basal end of said excitation optical fiber, and a spectroscope 127 connected to a basal end of said light receiving optical fiber', and an excitation light emitted from said light source 121/135 projected through said window via said excitation optical fiber 81 and Raman scattered by impinging on said matter adhered to the inside wall of said vessel, said scattered light being made incident to said window and spectrally analyzed by said spectrometer 127 via said light receiving optical fiber 83, and thus said matter adhered to the inside wall of said vessel being analyzed, column 7 through 9, more specifically column 7 lines 20-33 and column 8. Figures 6 and 7 and column 7 lines 20-33 clearly diagram and discuss, respectively, a single number of said excitation optical fiber 81 and plural number of said light receiving optical fibers 83 and at a distal end portion of said insert cable, said single number of excitation optical fiber 81 is arranged at a central area thereof and said plural number of light receiving optical

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fibers 83 are arranged in such a manner as to surround said excitation optical fiber 81.

Alfano et al. do not teach the distal end face of said light receiving optical fiber bundle to be orthogonal to a center axis of said bundle of light receiving fibers. Wach et al. teach the distal end of the excitation optical fiber to be slanted with respect to an axis of the bundle of light receiving optical fibers (abstract, col. 25 lines 5-7 lines 41-60, col. 26 lines 37-50, col. 27 lines 21-67, fig. 24-26). It would have therefore been obvious to one of ordinary skill in the art to use the slanted optical fiber teaching by Wach et al. to modify the teaching by Alfano et al. for the purpose of providing a controlled light transmission and detection and therefore a more efficient analysis of the tissue.

Regarding claims 13 and 14, Alfano et al. do not teach a film-like excitation filter adhered to the distal end of excitation optical fiber, a film-like filter adhered to the distal end of the receiving optical fiber. Wach et al. disclose an apparatus for analyzing matter adhered to the inside wall of a vessel comprising a guiding apparatus and a Raman analysis apparatus with a film-like excitation filter adhered to the distal end of excitation optical fiber, a film-like filter adhered to the distal end of the receiving optical fiber (col. 34 lines 18-67, col. 44 lines 21-65, col. 45 lines 12-29 lines 37-58, col. 46 lines 55-57, col. 47 lines 20-39, col. 49 lines 18-33, col. 50 lines 13-38, col. 52 lines 54-67, col. 64 lines 14-25). It would have therefore been obvious to one of ordinary skill in the art to have deposited/adhered the film-like filters onto the ends of optical fibers as taught by Wach et al. into the probe system of Alfano et al. for the purpose of allowing effective and efficient manipulation of the light delivery and reception region during Raman analysis.

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Regarding claim 15, Alfano et al. column 9 lines 9-28 recites that the endoscope 141 (interpreted as the guiding apparatus of the applicant) is sized and shaped to fit within an artery or other blood vessel.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for relevant references of interest.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

B. R.

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